



Tofflon

Tofflon Group Introduction

Partner of Bio-Support

2024-05-15

Expertise in Biopharmaceutical



CONTENTS

- 1. Vision and Strategy**
- 2. History and Organization**
- 3. Product Innovation**
- 4. Global Markets**
- 5. Advanced Manufacturing**
- 6. Next Development**

Vision and Strategy



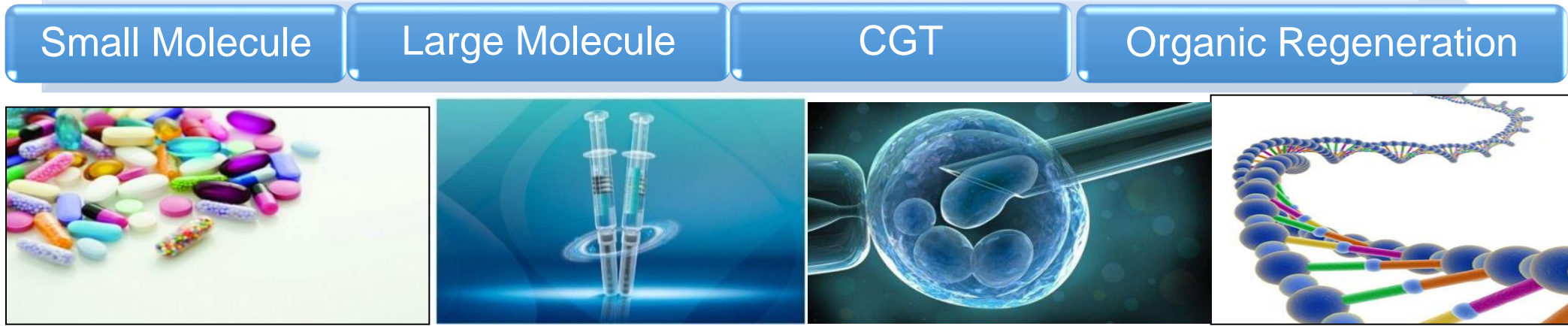
TGM 254
GDR 2 325.4

25/24
34.57
20 24

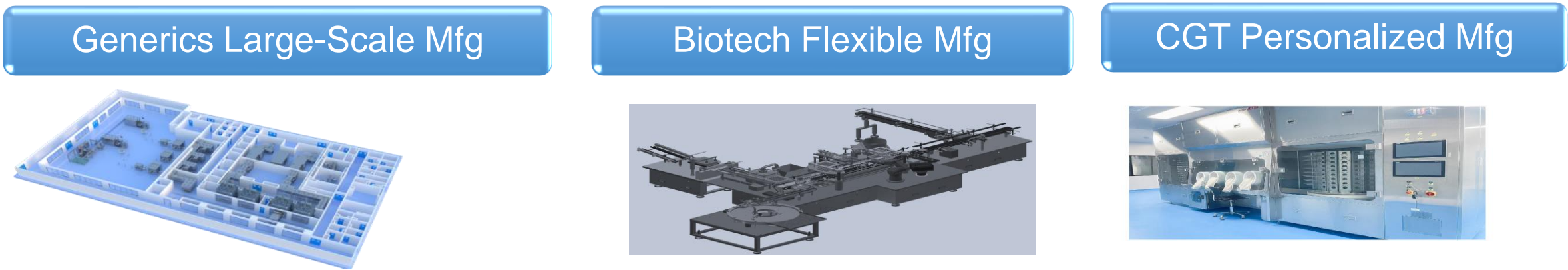
GTR 547
G47

TRACKING
RETINA PATH

Drug Innovation



Drug Manufacturing



Tofflon Vision

Tofflon

$(M+E+C)^{AI}$

M: Machinery, Device

E: Engineering

C: Consumables

AI: Digitalization

Smart Pharma Factory Builder

Tofflon Strategy

Tofflon

**Solution
Provider**



**Global
Tofflon**



**Digital
Tofflon**



History and Organization



Tofflon Growth History

Tofflon



Key Business Data

Tofflon



+30 Years
Expertise



50 Countries
& Regions
Installations



+2800
Customers
Worldwide



+5000
Employees



Global JV and
Tech Partners
Kyowac (Japan)
Top (Japan)
Airex (Japan)
Itema (Italy)
Praxair (USA)



USD 800M
(RMB 5.6B)
Sales Revenue
(2023)

Tofflon Global Joint Ventures and Technical Partners

Tofflon

Freeze Dryer

KYOWAC

LN₂ Refrigeration Freeze Dryer

PRAXAIR

Auto Solution Preparation Systems

TOPSYSTEM

Barrier Systems

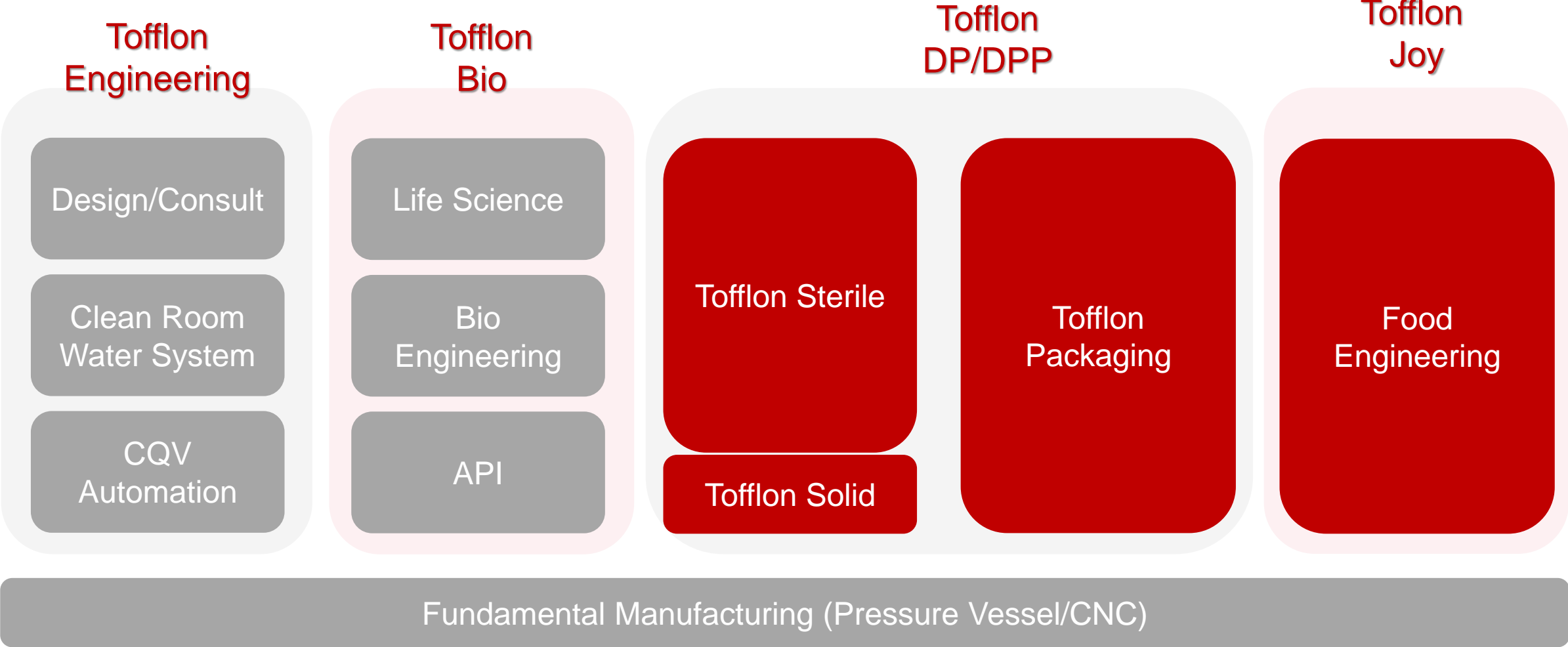
Airex

Fill-Finish Equipment and Line

itema

Tofflon Business Units

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Product Innovation



Application: Clinical Study Service

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Tofflon Labs

“Drug Smell”

- Injectable Lab
- Bio Lab
- CGT Lab
- OSD Lab

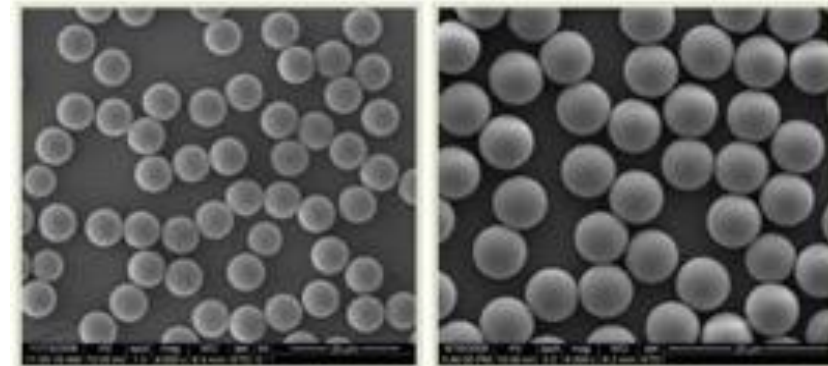
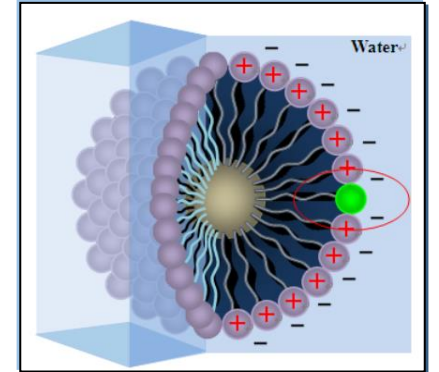
“Process Engineer” Value

(“Process Knowledge + Equipment Knowledge”)

- Process Scale-up
- Process Optimization
- Process Transfer
- Process Validation
- PAT
- DOE
- New Packaging Containers

Applications

- Lyo Tablet
- Dual-Chamber Syringes
- Microsphere
- Liposome
- Nano Emulsion
- Micelle



Joint R&D Hot Applications

Tofflon



Dual-Chamber Syringe

双腔体冻干注射剂



Auto Injector

注射笔



Freeze Dried Ball

球冻干



Lyo Tablet

冻干口崩片



Soft Mist Inhaler

软雾吸入剂



Oral Thin Film (OTF)

口溶膜

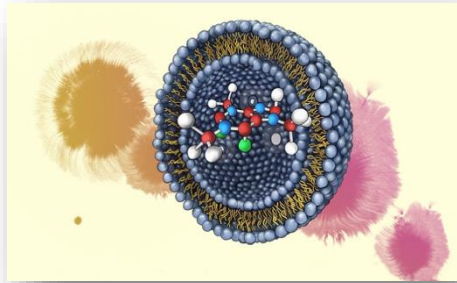


Transdermal Patch

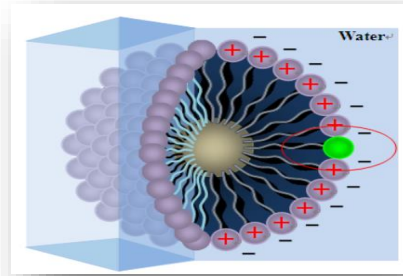
透皮贴

Joint R&D Hot Applications

Tofflon



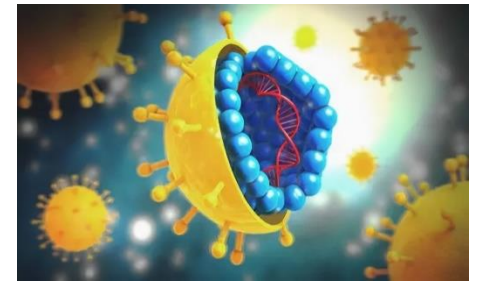
Liposome
复方脂质体



Micelle
胶束



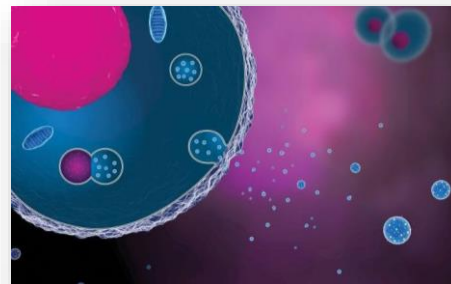
Radioactive Drug
放射性药物



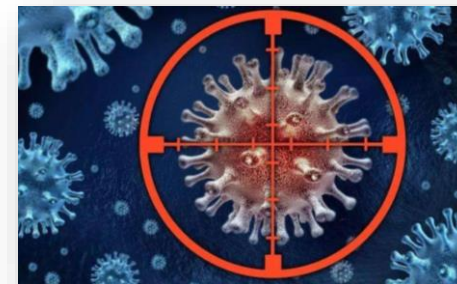
Adeno-Associated Virus (AAV)
腺相关病毒



mRNA



Exosomes
外泌体



Oncolytic Virus
溶瘤病毒



Synthetic Biology
合成生物

Application: Advanced Injectables

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Tofflon Innovations for Advanced Injecabels and Complex Injectables

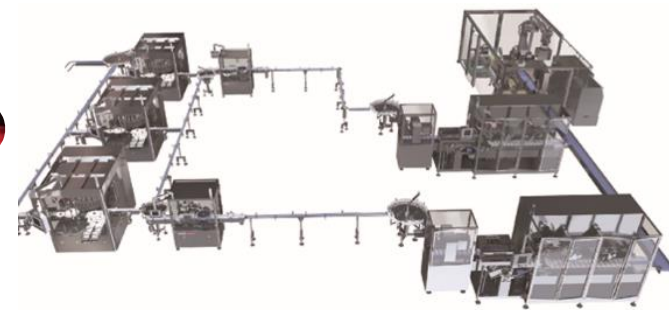
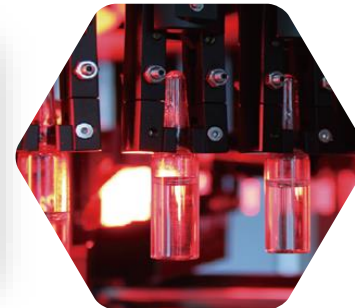
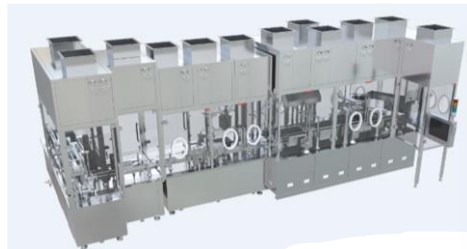
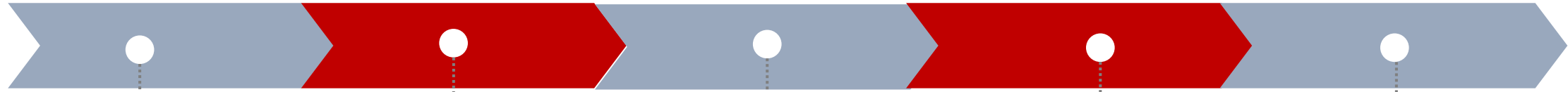
Compounding

Filling

Lyophilization

Inspection & Detection

Packaging



Application: Advanced Injectables

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KUFill – Advanced Injectables Manufacturing

- cGMP Compliance
- Modular Building Interfaces
- Automation and Isolation
- Systems Integration
- Flexible and Modular Equipment
- Expandable Factory
- More New Technologies
- Integrated Project Management
- Strong Technical Support and Service





No.	Filling & Lyophilizer	Num.
1	Vial Washer	1
2	Depyrogenation Tunnel	1
3	Filling and Stoppering	1
4	Capper for Vials	1
5	Isolator + ORABS System	1
6	oRABs for Capping	1
7	SCADA HMI	1
8	Lyophilizer (10m ²)	1
9	CIP Skid for LYO (2x3m ³)	1
10	Auto Loading & Unloading System (RBR)	1
11	AHU& EHU-01 for Filling	1
12	AHU& EHU-02 for ALUL (RBR)	1



Application: Biotech and Biopharma

Tofflon Innovation for Biotech and Biopharma

Bioreactor



Purification



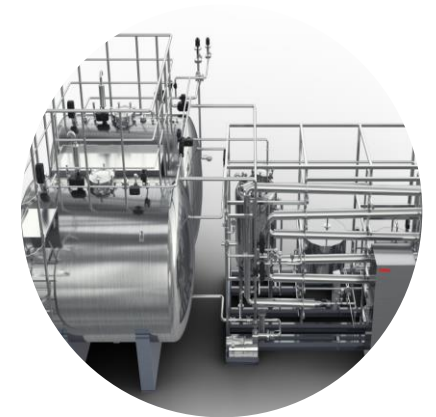
Freezing
Thawing



Media/Buffer
Preparation



Inactivation



Application: Biotech and Biopharma

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mAbs

- SUS/SS Bioreactor
- Media/Buffer Preparation and Holding
- Purification & Separation

- BeiGene、Henlius
- Wuxi Biologics、Cheerland
- Hualan、Suncandia
- Lonza、Stelis



Bio Consumables (Bags/Media/Resin/Filter Membrane)

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Application: Vaccine

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Covid-19 Vaccine Production

Lines

- Inactivated Vaccine
- Adenovirus Vector Vaccine
- Recombinant Protein Vaccine
- mRNA Vaccine

DS (Upstream), DS (Downstream),
DP (Primary Packaging and
Secondary Packaging)

China, France, Korea, India,
Vietnam, Argentina, Morocco,
Uzbekistan, etc.



Inactivated COVID-19 Vaccine Project

Tofflon

Customer: CNBG, China

Project: Phase One

Tofflon's Scope

- Total 104 tanks for media and buffer preparation and storage
- Stainless steel bioreactors
- Virus inoculation isolator
- QC isolator
- Chromatography system
- Ultrafiltration system



Inactivated COVID-19 Vaccine Project

Tofflon

Customer: CNBG, China

**Project: Phase Two
Coronavirus Vaccine (8 Lines)**

Tofflon's Scope:

- 8-1000L*2 Bioreactor storage tanks
- 8-1200L Virus harvest tanks
- 8-1200L Virus inactivation tanks
- 8-1200L*2 storage tanks for liquid to be tested
- 2-1200L and 600L concentration storage tanks
- 2 sets of double-tank CIP
- 1000L*7 media preparation tanks



Tofflon 拓普康

Application: CGT

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Upstream



**Single Use
Cell Processing**



**GMP Cell
Processing Station**



**Expandable Incubator
Storage Matrix**



**Single Use
Cell Jar**

Downstream



**MiniKUFill
Auto Cell Filling System**



**Programmable
Cooler**



**Manual
LN2 Jar**



**Auto LN2
Storage System**



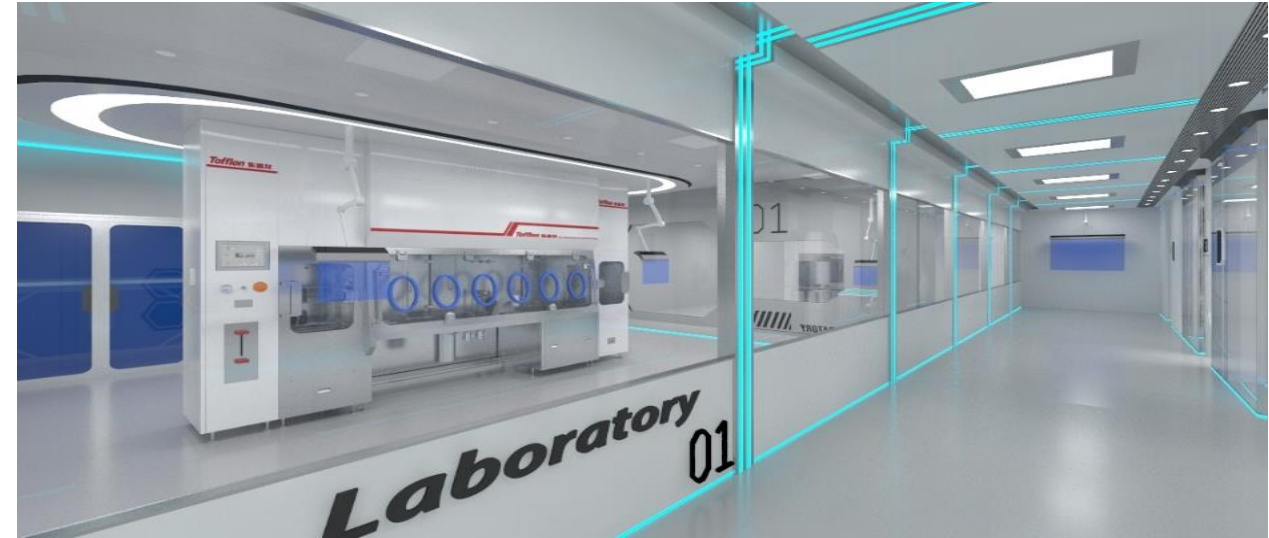
**Small-Volume
Auto LN2 Storage System**

Application: CGT

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Sichuan University New Drug R&D and Manufacturing Platform

- T-Cell Production Line
- CAR-T Production Line
- Cellular Vaccine Production Line
- Lentiviral Vector Production Line
- LNP Production Line
- mRNA Production Line



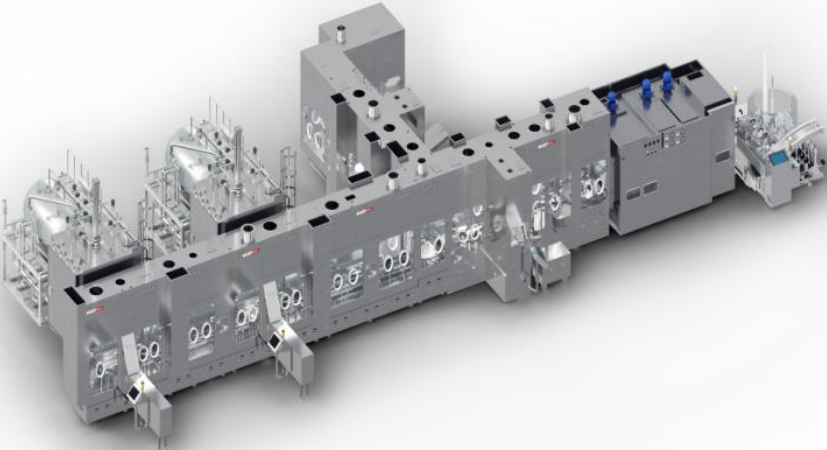
Tofflon Bio Modular Factory (Oncology/Insulin/Vaccines/mAbs/CGT)



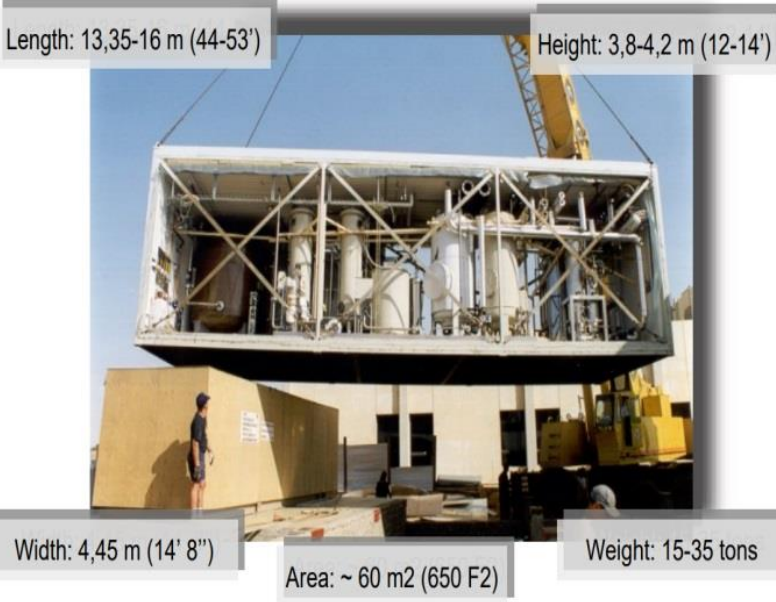
DS Equipment & System



DP Equipment & System

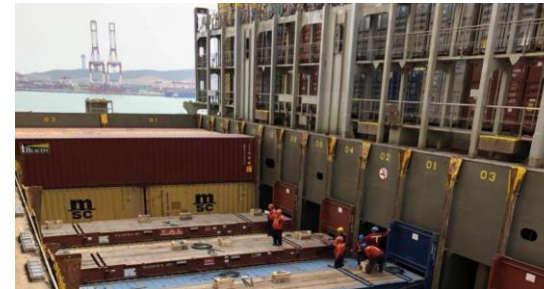
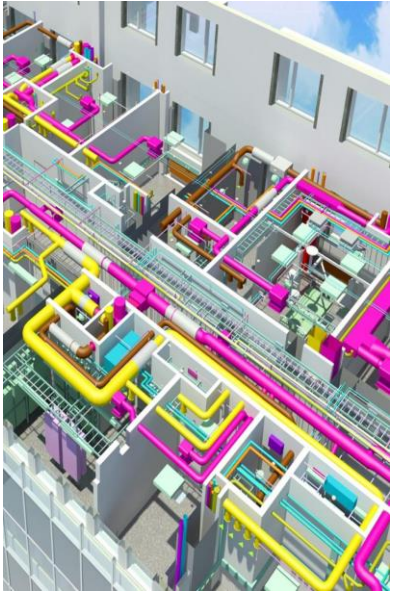


Modular Facility (DS & DP Facility)



Tofflon Service Scope of Tofflon Bio Modular Factory

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Concept Design	Detailed Design	Offsite (Inhouse) Fabrication	Transportation	Onsite Construction	Handover
<ul style="list-style-type: none"> 1、PFD/URS 2、Regulation, Risk Analysis, Feasibility Study 3、Proposal Analysis 4、Project Budget 	<ul style="list-style-type: none"> 1、BIM Design 2、Construction Drawing 3、Fabrication Drawing 4、Evaluation Report 5、Estimated Cost 	<ul style="list-style-type: none"> 1、Steel Structure Module 2、Steel Structure 2、Electromechanical Installation 3、Equipment Installation 4、Commissioning and FAT and Prequalification 	<ul style="list-style-type: none"> 1. Land Transport: concave heart flatbed truck 2. Shipping: frame cabins, bulk carriers 3. Warehousing and transportation team 	<ul style="list-style-type: none"> 1. On-site civil construction 2. The module is secondarily connected 3. Façade construction 4. Schedule management, quality management, cost management 	<ul style="list-style-type: none"> 1. Process equipment debugging 2. Commissioning of public works equipment 3. Linkage debugging 4. Verify the documents

Tofflon's Modular Factory: Added Innovations and Values



Besides general modular facility advantages, Tofflon's Modular Factory Solution is developing the following added innovations and values to better solve many practical needs and challenges:

- ✓ **One-Stop Service: minimize complex interfaces** of many suppliers and sub-contractors
 - Tofflon can **One-Source Supply** Modular Facility and Engineering, DS Equipment (Hybrid System: SUS & SS), DP and DPP Equipment (Fill-Finish) and Clean Utility (Cleanroom, HVAC, Water System and Distribution System, etc) from A to Z.

- ✓ **Key equipment pre-assembled, pre-engineered and pre-tested** will be integrated into modular unit to **further secure on-site quality, timeline and cost**
 - Customized developed DS stainless steel equipment (for example media and buffer skid and pipeworks) for cross modular units
 - Customized developed DP equipment (for example isolated filling line and freeze dryers) for cross modular units

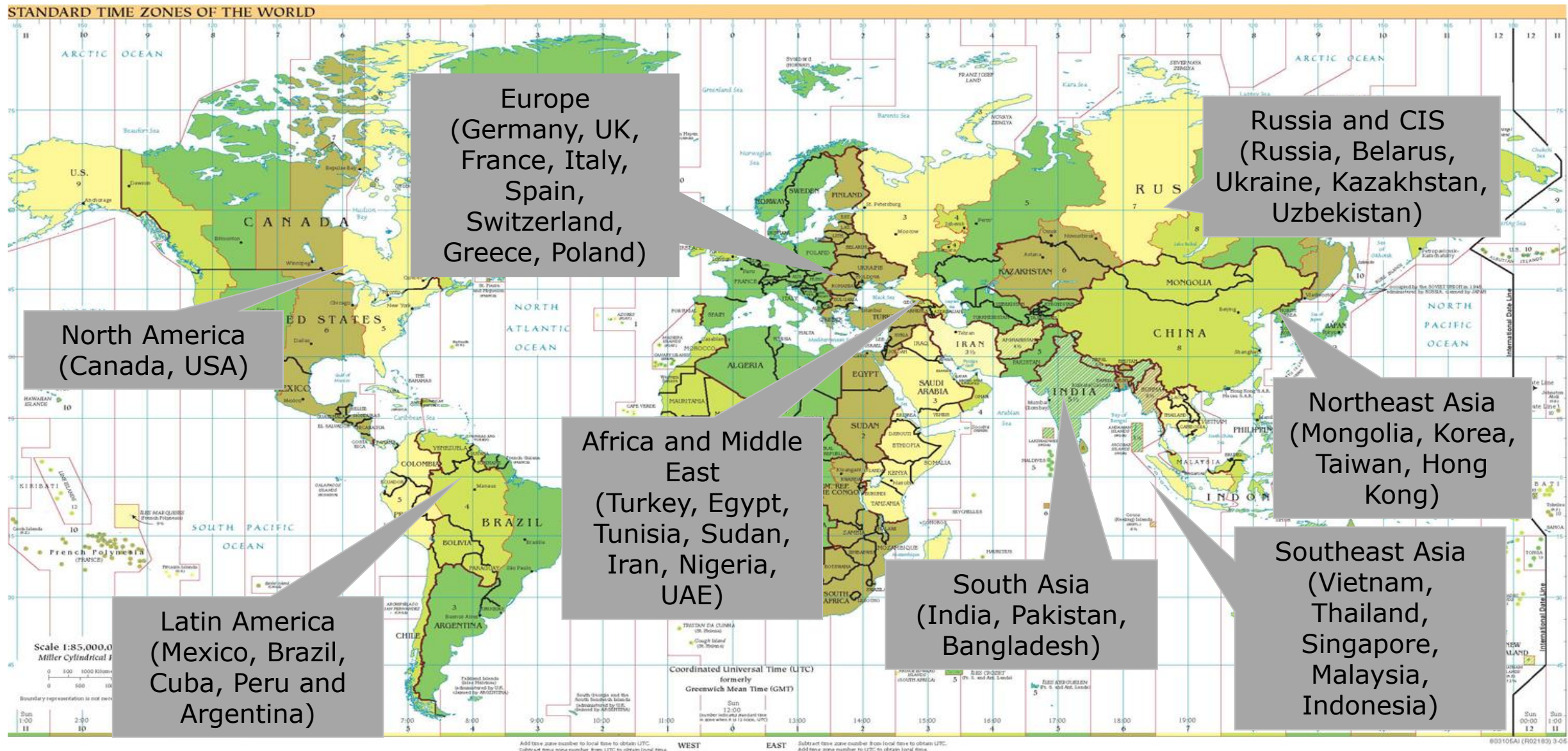
- ✓ **Strengthened Technical Support** for Start-Up Biotech Customers
 - Process Support (mAbs, vaccine, biosimilars and CGT)
 - Pre-qualification documentation support in compliance with international GMP regulation
 - Technical training and PQ support to develop local biotech talents
 - Bio Consumable Strategic Supply Agreement

A large group of approximately 50 people, mostly men in business suits, are posing for a group photo. They are arranged in several rows, with some standing on the ground level and others on a balcony above. The balcony has a decorative stone railing with arched openings. The building is a light-colored stone or concrete structure with large windows and a classic architectural style. The text "Global Markets" is overlaid in the center of the image in a bright yellow font.

Global Markets

50 Countries and Regions Installations Since 2004

Tofflon



Our Typical Customers in Each Niche Market

Tofflon

Small Molecule

Brand Drugs



Generic



Large Molecule

mAbs、ADC



Vaccine



Insulin



Plasma



Cell/Gene Therapy

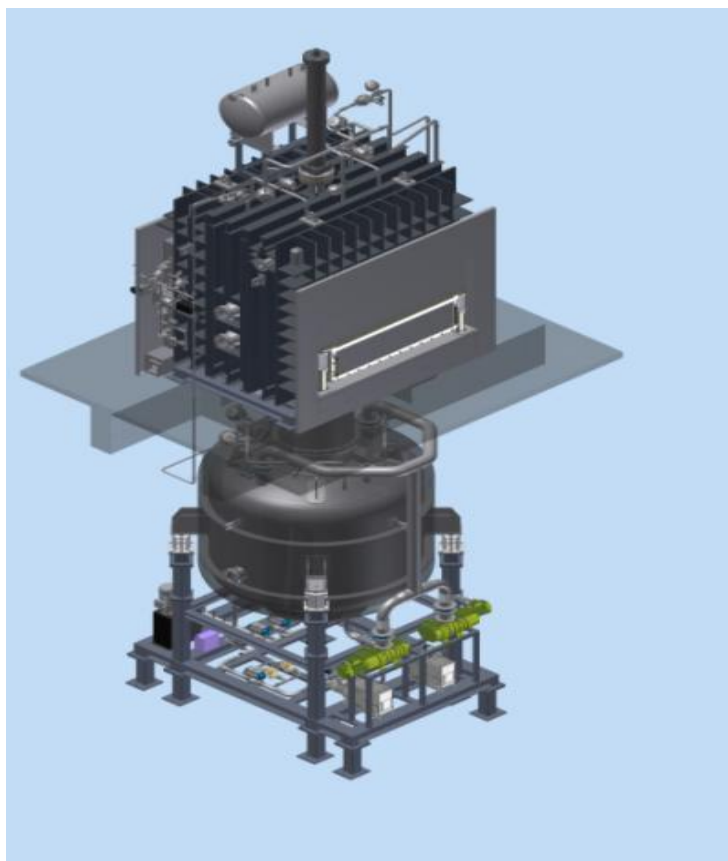


Part of Multinational Pharma Customers

Tofflon



2 x LYO-38(SIP,CIP)

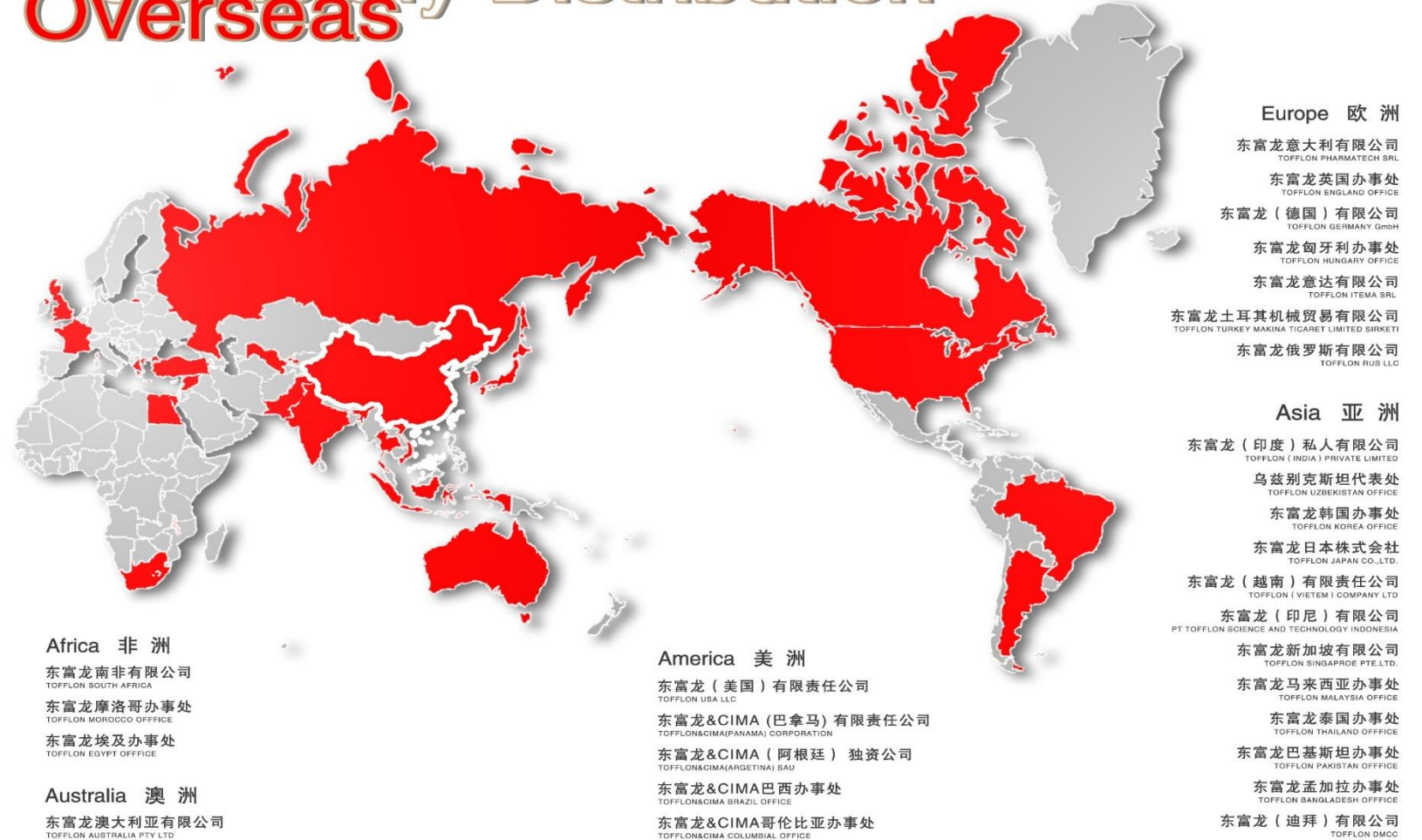


Global Sales Network

Tofflon

- Region: South Asia, SEA, Russia, CIS, MENA, Latin America, Europe and North America
- Subsidiary: 10 Regional Operation Centers
- Representative Office: 20

Company Distribution Overseas



Advanced Manufacturing



6 Current Manufacturing Parks in China

Tofflon



- German TUV ISO 9001 Quality Assurance System
- European PED Pressure Vessel
- American ASME Pressure Vessel
- European CE and American UL Compliance
- Control System Compliant with GAMP5
- USFDA 21 CFR Part 11 Guidelines



New Manufacturing Centers

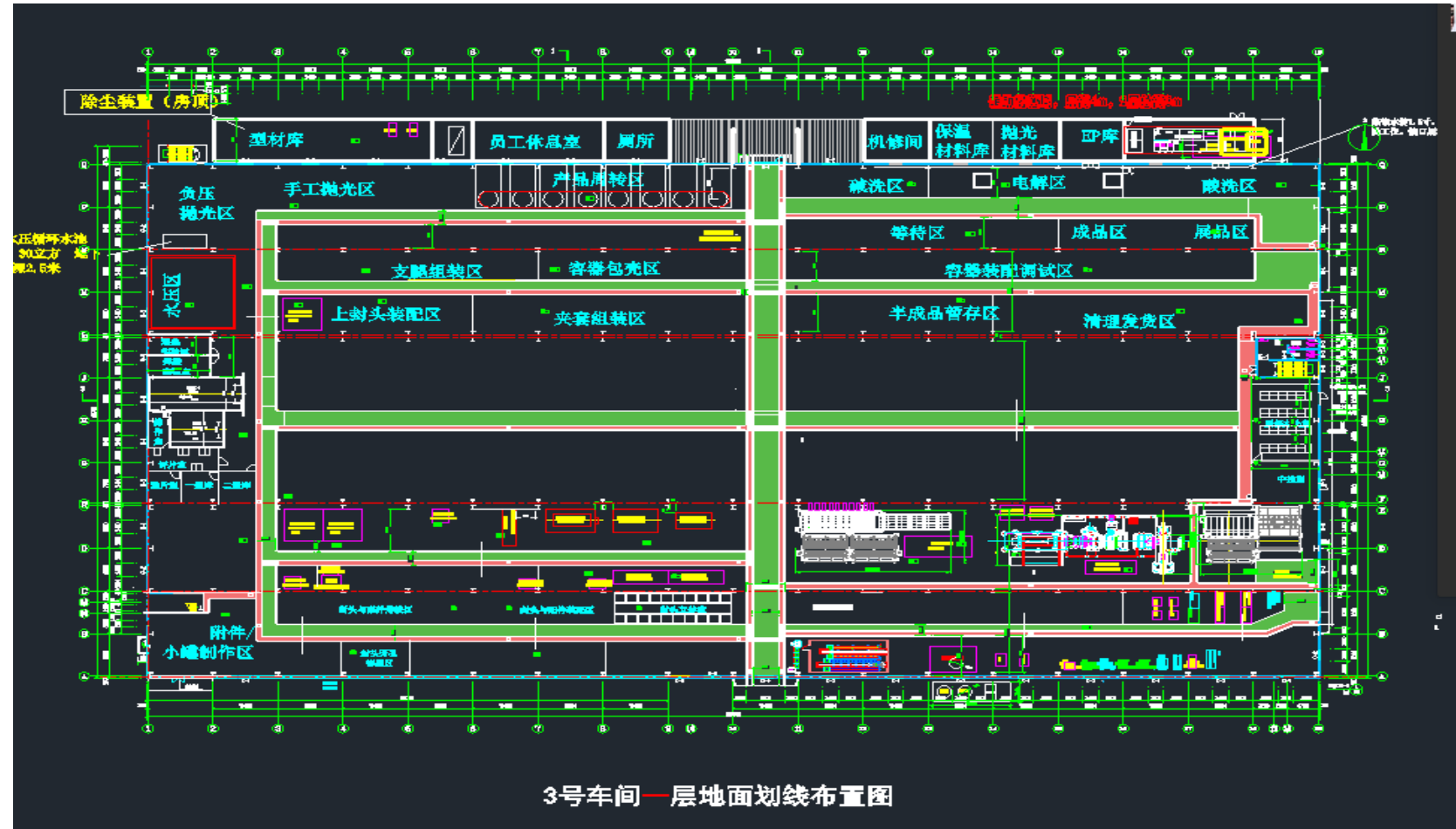
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Jiangsu Dongtai: New Fundamental Manufacturing Base
(DP/DPP Equipment/Food Engineering/Modular Module)



Digital Manufacturing

- Lean Manufacturing
- 5S Site Management
- Digital Twins
- Welding Cloud Management
- MES
- AGV
- Auto Warehouse Management



New Manufacturing Centers

Tofflon

Jinshan Bio Manufacturing Park: One of the Largest Bio Equipment Manufacturing Bases in Asia





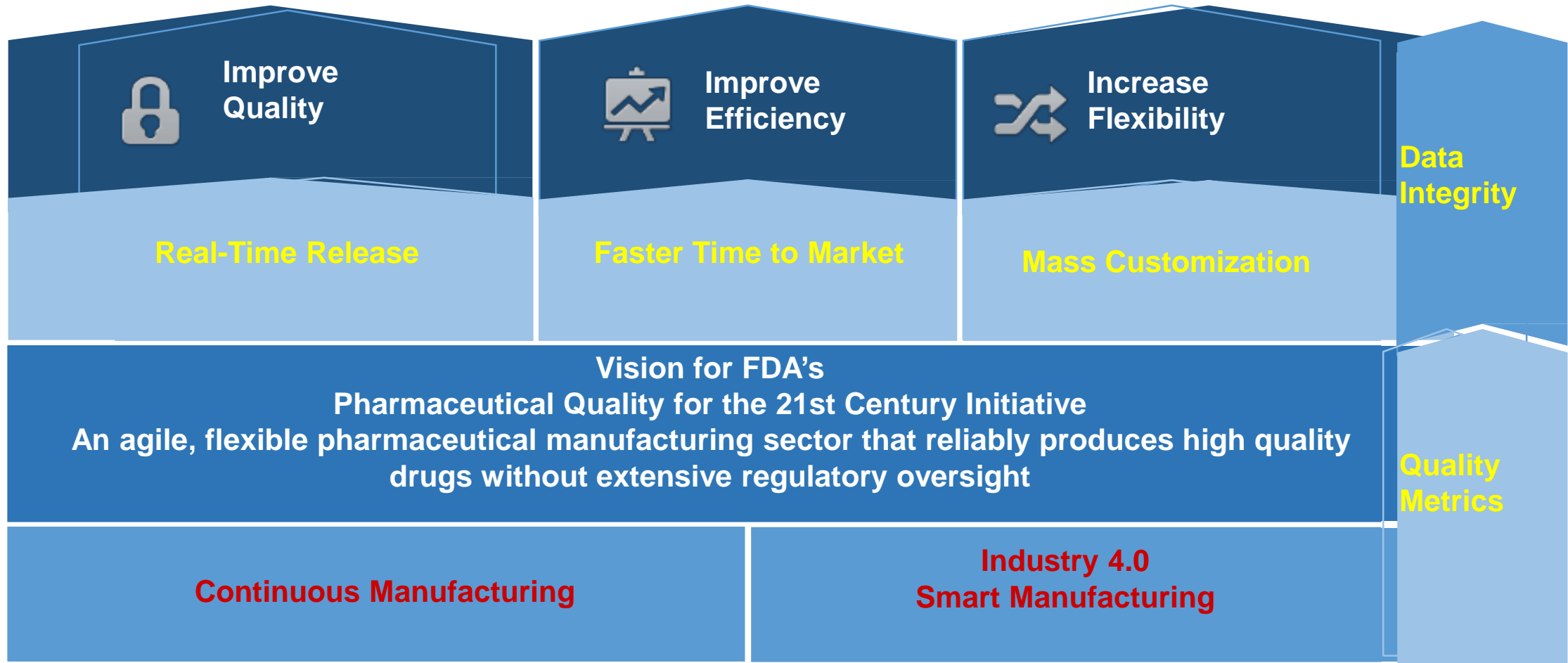
Next Development

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Next Generation Drug Manufacturing

Tofflon



**Balance between Quality and Efficiency,
Coordination between Compliance and Flexibility**

Key Niche Markets

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Advanced Injectables

Biopharma, CGT

Synthetic Biology
& API New Applications

Oncology
Complex Injectables
New Delivery Administration
BFS

PD1/PDL1
Polyclonal Antibody
ADC, PDC
Vaccine, mRNA
CMO, CDMO

Polypeptide Synthesis
Enzyme Conversion
Heparin Sodium
Insulin
Small Nucleic Acid
Probiotics

Strategic Investment 2: R&D Investment (Annual Sales Revenue x 6-8%)

Tofflon

Advanced Injectables

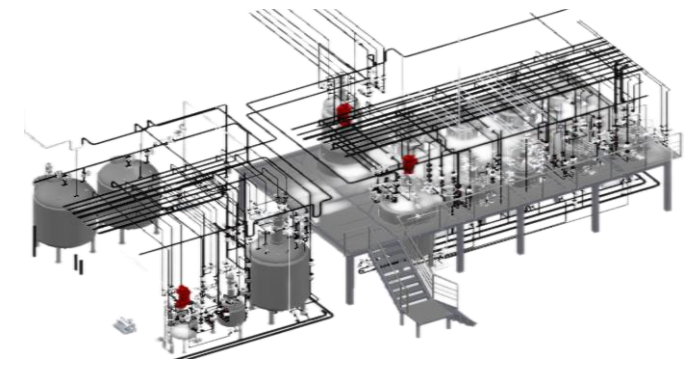
- Complex Injectables
- Key Equipment:
Freeze Dryer and Filling Line
- New Packaging Containers
- Digital Machine and Service
- Continuous Manufacturing & PAT

Biopharma and CGT

- SUS
- Bio Consumables
- Large-Scale Bioreactor
- Key Purification Equipment
- Process Lab

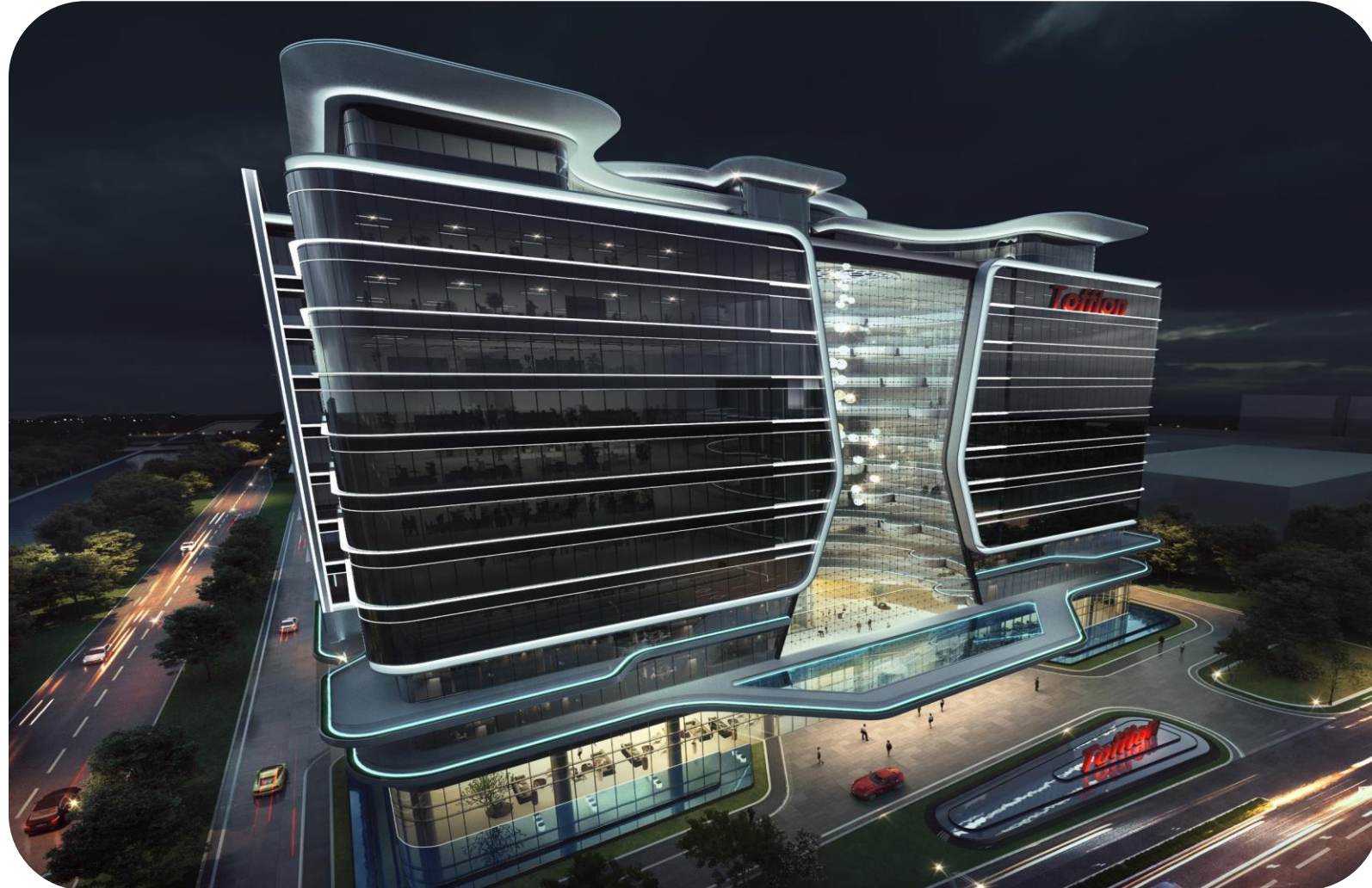
Synthetic Biology

- Fermentation
- Separation and Purification
- Drying



Strategic Investment 2: R&D Investment

Tofflon



**Tofflon Global
R&D Center**

Strategic Investment 3: Life Science Investment

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Tofflon
(Hangzhou) Life
Science Base

Tofflon In Next 10 Years (2023-2033)

Tofflon

Medical

Innovation: CGT, Organic Regeneration

Pharma

Integration: Smart Pharma Factory Builder

Food Engineering

Growth: Food Engineering (E+M +C)

2033

**Tofflon:
Expertise for
Human Healthcare**

Tofflon

**Tofflon Vision:
Smart Pharma Factory Builder**

**Warmly Welcome
To Tofflon**

